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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,613	06/27/2001	Shawn Shui-on Leung	655	4914

7590 06/07/2005

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Whitestone, NY 11357

EXAMINER
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HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/892,613

Applicant(s)

LEUNG, SHAWN SHUI-ON

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/1/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/05 has been entered.
2. Claims 40-50 are pending and are under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. It is noted that the RCE filed 3/17/05 requested that the amendment filed 6/26/04 be considered. This amendment was considered and addressed in the final Office Action mailed 9/13/04 and will be reiterated in the rejections below because the response filed 4/1/05 did not add any new arguments.

### ***Rejections Withdrawn***

5. The rejection of newly added claims under 35 U.S.C. 102(b) as being anticipated by Ohtomo et al (Molecular Immunology 32:407-416, 1995) is withdrawn in view of the amendments to the claims.

### ***Response to Arguments***

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6. The rejection of newly added claim 50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed 4/1/05 has been carefully considered but is deemed not to be persuasive. The response states that support for claim 50 is supported by previous claim 39 (see page 8 of response). In response to this argument, previous claim 39 was for a pharmaceutical composition and in fact was not examined and does not support the claimed limitation.

7. The rejection of newly added claims 40-50 under 35 U.S.C. 103(a) as being unpatentable over Ohtomo et al (Molecular Immunology 32:407-416, 1995) and further in view of Queen et al (US Patent 5,693,762, issued 12/97, IDS #11/2) is maintained.

The response filed 6/28/04 has been carefully considered but is deemed not to be persuasive. The response argues residues re-introduced are different in framework-patching than in Queen et al (see page 22-24). In response to this argument, the claims requiring re-introducing residues only require replacement of residues adjacent or within a certain distance to a CDR there is nothing in the claims requiring the re-introduced residues not being murine.

The response then states that FR1, FR2, and FR3 should be intact in the Queen reference and Ohtomo does not teach altering the FR1, FR2, or FR3 (see page 25-27). In response to this argument, Ohtomo et al clearly teaches looking for the most homologous FR from the human database or consensus sequence. Ohtomo et al teach comparison of the Fr wherein each is compared. Therefore, it would be obvious to have

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a FR1 from one immunoglobulin and FR2 from another if the most homology was found in a different immunoglobulin (wherein FR1 was most homologous to one human immunoglobulin and FR2 was most homologous to another immunoglobulin). This is because Ohtomo et al chose FR4 to be different based on homology to another immunoglobulin. In addition, Ohtomo teach FR1 and 2 from a mouse and FR3 and 4 from human in the light chain (see page 412). Therefore, the method of Ohtomo would use comparisons of each FR.

The response further argues methods of the invention vs. Queen and Ohtomo and which residues to back mutate (see pages 29-31). In response to this argument, the claims are to products not methods and as stated above the products are the same as claimed and in the prior art and the claims only require replacement of residues adjacent or within a certain distance to a CDR there is nothing in the claims requiring the re-introduced residues not being murine.

The response then states that the homology of Ohtomo and Queen is in the context of the whole FR sequence and not individualized Fr and this is unprecedented (and assumed to be the invention) (see page 31). In response to this argument, Ohtomo et al teach comparison of the Fr wherein each is compared. Therefore, it would be obvious to have a FR1 from one immunoglobulin and FR2 from another if the most homology was found in a different immunoglobulin (wherein FR1 was most homologous to one human immunoglobulin and FR2 was most homologous to another immunoglobulin). This is because Ohtomo et al chose FR4 to be different based on

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homology to another immunoglobulin. Therefore, the method of Ohtomo would use comparisons of each FR.

8. The rejection of newly added claims 40-44, 46-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 4/1/05 did not address this rejection and as such it is maintained.

### ***Conclusion***

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached on (571) 272-0787.


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11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



**LARRY R. HELMS, PH.D**  
**PRIMARY EXAMINER**